

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

COI – P 1 of 5

SOP# HRP 01.17

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CONFLICT OF INTEREST (COI)

OBJECTIVES:

- To establish the VAMHCS R&D Committee (RDC) as the Research Conflict of Interest (COI) Committee when the following occurs:
 - 8/8 VAMHCS investigators serving as site PI's for VA Cooperative Studies Program (CSP) studies and who do not have academic appointments (and the University is therefore not engaged in the research),
- To establish the process to identify, evaluate and manage any perceived or actual conflicts of interest involving the research projects brought before the VAMHCS R&D Committee (RDC).
- To preserve and enhance integrity of research activity that could be subject to intentional or unintentional bias as a result of real or unintentional bias as a result of real or perceived institutional conflict of interest (ICOI)

SCOPE & POLICY:

This SOP applies to all human research projects submitted to the VAMHCS R&D Committee (RDC).

Most human research projects come to the RDC after prior review & approval by the UMB IRB. This review includes an evaluation of financial disclosures of investigators and research team members by the UM conflict of interest officer (COIO) and subsequent development of a COI management plans if necessary.

Some research, where the principal investigator is an 8/8 VAMHCS investigator serving as a site PI for a VA Cooperative Studies Program (CSP) study and who does not have an academic appointments (and the University is therefore not engaged in the research), requires an alternative route for evaluation of COI for the investigator and research team.

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The impact of conflicts may occur in any phase of the project, from the development of the project design to management and oversight of an approved project. Conflicts may also bias project reviews, analysis of data, and dissemination of the project results through publications and presentations.

All VAMHCS investigators and research team members must comply with VA and University of Maryland Baltimore (UMB) (as applicable) requirements relating to conflict of interest. This includes disclosure of any perceived or actual conflicts of interest.

Additionally, VAMHCS RDC and subcommittee members, whether voting or nonvoting, are required to disclose any perceived or actual conflict of interest according to the requirements in this SOP.

This SOP also addresses perceived or actual institutional conflict of interest within the VAMHCS. At the VAMHCS, potential institutional COI is most likely to occur through technology transfer agreements, large contracts, or other means. The threshold amount of >\$1 million/year from a single sponsor could represent institutional COI (VA and NIH sponsorship excluded).

DEFINITIONS

Conflict of Interest (COI). Any situation in which financial or personal obligations or interests may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research. An appearance of COI is when the circumstances would cause a reasonable person with knowledge of the relevant facts to question an employee's impartiality in the review and conduct of human research protocols.

Institutional Conflict of Interest (ICOI). A significant financial interest or significant relationship which may compromise the institution's research activity. ICOI may be present or be perceived to be present when the VAMHCS, its senior leadership, or its investigators and scientists involved in specific VAMHCS research activity have a significant financial interest or when the VAMHCS has a significant relationship with persons who are identified with entities (1) that are sponsors of research activity or (2) that have an interest in the outcome of research activity. The threshold amount of >\$1 million/year from a single sponsor could represent institutional COI (VA and NIH sponsorship excluded).

Financial Interest. Financial interests are limited to those owned by the employee or by the employee's spouse or minor children. It includes any current or contingent ownership, equity, or security interest in real or personal property or a business and may include an indebtedness or compensated employment relationship. It includes interests in the nature of stocks, bonds, partnership interests, fee and leasehold interests, mineral and other property rights, deeds of trust, and liens. It extends to any right to purchase or acquire any such interests, such as a stock option or commodity future. It does not include a future interest created by someone other than the employee, the employee's spouse, or dependent child or any right as a beneficiary of an estate that

has not been settled. It does include service, with or without compensation, as an officer, director, trustee, general partner, or employee of any person, including a nonprofit entity, whose financial interests are imputed to the employee (5 CFR 2635.403(c)).

RESPONSIBILITIES:

1. The ACOS/R&D is responsible for:
 - Disclosing potential conflict of interest (if applicable) according to this SOP;
 - Notifying the VAMHCS R&D Committee of technology transfer agreements, large contracts or any other cases of potential institutional conflict of interest (COI).
2. The Deputy ACOS/R&D is responsible for:
 - Disclosing potential conflict of interest (if applicable) according to this SOP;
 - Notifying the ACOS/R&D of technology transfer agreements, large contracts or any other cases of potential institutional conflict of interest (COI).
3. The Executive Director, Baltimore Research & Education Foundation (BREF) is responsible for:
 - Notifying the ACOS/R&D of technology transfer agreements, large contracts or any other cases of potential institutional conflict of interest (COI).
4. The University of Maryland Conflict of Interest Officer (COIO) is responsible for:
 - Notifying the VAMHCS Research COIO of any cases of potential COI identified for non-UMB affiliated research team members;
 - Carrying out IRB policies & procedures regarding evaluation and management of COI or ensuring that a committee follows these procedures.
5. The VAMHCS Research COI Officer (RCOIO) is responsible for:
 - Notifying the RDC of any cases of potential COI identified for non-UMB affiliated research team members;
 - Notifying the UMB IRB or the VA CIRB of the RDC's discussion and any determinations or recommendations.
6. The UMB IRB is responsible for following its policies and procedures regarding evaluation and management of conflicts of interest.
7. VA R&D Committee is responsible for:
 - Reviewing the findings of the IRB's COI evaluation and management plan and making any other appropriate recommendations;
 - Communicating these recommendations to the investigator and the IRB.
8. The Principal Investigator and Research Team Members are responsible for:
 - Complying with UMB policies and procedures for disclosure of perceived or actual conflicts of interest.
 - Complying with UMB IRB, VA CIRB or VAMHCS RDC approved management plans for COI (if applicable).

9. The IRB is responsible for review and approval of actions and corrective action plans in accordance with VHA Directive 2008-072 and IRB Policies and Procedures. (see Procedure 5 below).

PROCEDURE:

1. Investigator and research team member potential COI related to human research activities and the principal investigator (PI) has a UM faculty appointment.
 - 1.1. When new studies are submitted to the UMB Institutional Review Board (IRB) by a principal investigator with a University of Maryland faculty appointment, the investigator and all research team members must complete the CICERO “Financial Disclosure Statement” and submit it into CICERO before the study can proceed through the IRB review process.
 - 1.2. CICERO automatically sends the “Financial Disclosure Statements” directly to the UMB COI Officer (COIO) to be screened for potential financial conflict of interest.
 - 1.1.1. If the UM COIO determines that an investigator or research staff has reported a financial interest related to the research **and** the research staff¹ is a UM employee, the UM COI proceeds according to UM HRPO policies and procedures. The end result is for the IRB to be provided with the COI evaluation and management plan.
 - 1.2.1. If the UM COIO determines that an investigator or research staff has reported a financial interest related to the research **and** the research staff² is **not** a UM employee, the UM COIO notifies the VAMHCS Research COIO via email or other written communication.
 - 1.3. If 1.2.1 applies, the VAMHCS Research COIO presents the case to the Research & Development Committee (RDC) who will review the potential COI. The RDC, in consultation with VA Regional Counsel (when necessary), will develop a COI management plan. The VAMHCS Research COIO will notify the UMB IRB or the VA Central IRB (whichever is applicable) of the RDC’s discussion and any determinations or recommendations.
2. Investigator and research team member potential COI related to human research activities and the principal investigator (PI) **does not** have a UM faculty appointment.
 - 2.1. If an investigator is not affiliated with the University (for example, 8/8 VA investigators who are submitting to the VA CIRB):
 - 2.1.1. The investigator and research team members complete the VAMHCS “Financial Disclosure Form” as part of their local submission process to the CIRB.
 - 2.1.2. The VAMHCS Research COIO reviews the VAMHCS “Financial Disclosure Forms” of the investigator and research team.
 - 2.1.3. If potential financial COI is evident, the VAMHCS Research COIO presents the case to the RDC who will review the potential COI. The RDC, in consultation with VA Regional Counsel (when necessary), will develop a

¹ Most VAMHCS investigators are dually-appointed with the University of Maryland.

² Most VAMHCS investigators are dually-appointed with the University of Maryland.

COI management plan. The VAMHCS Research COIO will notify the VA Central IRB of the RDC's discussion and any determinations or recommendations

3. Institutional COI:

- 3.1. The Deputy ACOS/R&D notifies the ACOS/R&D at the time that a VAMHCS technology transfer agreement is initiated.
- 3.2. The Executive Director of the VAMHCS nonprofit (BREF) notifies the ACOS/R&D at the time that a large contract for research services is initiated.
- 3.3. Other individuals may also notify the ACOS/R&D when the institution, or any of its senior management, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research project.
- 3.4. The ACOS/R&D notifies the RDC who will review the potential institutional COI.
- 3.5. The RDC, in consultation with VA Regional Counsel (when necessary), will develop a COI management plan.
- 3.6. The VAMHCS Research COIO will notify the UMB IRB or the VA Central IRB (whichever is applicable) of the RDC's discussion and any determinations or recommendations.

4. Conflict of Interest of IRB Members

- 4.1. Follow IRB policies & procedures.

5. Conflict of Interest of RDC Members

- 5.1. See VAMHCS Research Service HRP 01.03 "R&D Committee" (Procedure 2.5).

REFERENCES:

UMB HRPO SOP HRP-104	Institutional Conflicts of Interest
UMB HRPO SOP HRP-055	Financial Conflict of Interest
VA CIRB SOP 103	Managing Conflict of Interest